

JUN - 5 2000

Providing Solutions Through Innovation and Creativity



**Epic Medical Equipment Services, Inc.**  
1800 10TH STREET, SUITE 300, PLANO, TEXAS 75074

K000 831

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## 510(k) Summary

### **Submitter Information:**

Epic Medical Equipment Services, Inc.  
1800 E. 10<sup>th</sup> Street, Suite 300  
Plano, TX 75074

### **Contact:**

Krista Oakes  
Vice President, Regulatory Affairs and Quality Assurance  
Telephone: (972) 801-9854  
Fax: (972) 801-9859

### **Date Prepared:**

March 9, 2000

### **Product Name:**

Common Name: SpO<sub>2</sub> Sensor (accessory to pulse oximeter)  
Trade Name(s): Stat-Shell Disposable SpO<sub>2</sub> Sensor

### **Predicate Device:**

This product is a modification to the Epic 100 Series SpO<sub>2</sub> sensor marketed under 510(k) # K970098 and the Epic 500 Series Stat-Shell sensor marketed under K992092.

### **Description:**

The Stat-Shell Disposable SpO<sub>2</sub> Sensor is an electro-optical sensor which functions without skin penetration, electrical contact, or heat transfer. It is an accessory to compatible SpO<sub>2</sub> oximeters. The sensor uses optical means to determine the light absorption of functional arterial hemoglobin by being connected between the patient and the oximeter. The sensor contains three optical components: two light emitting diodes (LED) that serve as light sources and one photodiode that acts as a light detector.

The photodiode is housed in a textured, rigid ABS shell that is contoured for patient digit placement. The LED's are housed in a foam tape that is positioned over the nail bed and wrapped around the patient's digit.

The sensor cable is 2 feet in length and is terminated in DB-9 style connector.


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**Intended Use:**

The Stat-Shell Disposable SpO<sub>2</sub> Sensor is indicated for continuous, non-invasive functional arterial oxygen saturation and pulse rate monitoring for patients weighing more than 30 kg.

**Comparison to Predicate Device:**

|                                   | <b>Predicate Device –<br/>Epic 100 Series SpO<sub>2</sub><br/>Sensor<br/>(ref. # K970098)</b> | <b>Predicate Device –<br/>Epic Stat-Shell<br/>Sensor Model #<br/>E502-02 (ref.<br/>K992092)</b> | <b>Proposed<br/>Epic Stat-Shell<br/>SpO<sub>2</sub> Sensor –<br/>Model # E502-08</b> |
|-----------------------------------|---|---|--|
| Intended use                      | Continuous SpO <sub>2</sub> monitoring  | Continuous SpO <sub>2</sub> monitoring  | Continuous SpO <sub>2</sub> monitoring   |
| Anatomical sites                  | Finger/toe  | Finger/toe  | Finger/toe   |
| Target patient population         | > 30kg  | > 30kg  | > 30kg   |
| Accuracy claim                    | +/-3 digits @ 70%-100% SpO <sub>2</sub> +/- 1 std. deviation                                  | +/-3 digits @ 70%-100% SpO <sub>2</sub> +/- 1 std. deviation                                    | +/-3 digits @ 70%-100% SpO <sub>2</sub> +/- 1 std. Deviation                         |
| Patient use/reuse                 | Multi-patient reusable  | Single-patient/limited reusable (disposable)  | Single-patient/limited reusable (disposable)   |
| Sterility                         | Non-sterile device  | Non-sterile device  | Non-sterile device   |
| Description of patient attachment | Hard ABS outer shell, spring clip, soft finger pad  | Rigid ABS shell, adhesive foam tape   | Rigid ABS shell, adhesive foam tape  |
| Cable length                      | 3 – 12 feet   | 2 feet  | 2 feet   |
| Accessories                       | Adapter cables and extension cables   | Adhesive strips for single patient reuse<br>Accessory extension cable                           | Adhesive strips for single patient reuse<br>Accessory extension cable                |
| Oximeter compatibility            | Multiple  | Ohmeda oximeter   | Nonin oximeter   |
| Connector design                  | Various, including DB-9 connector   | DB-9 connector with DB-9/Hypertronics connector adapter cable                                   | DB-9 connector   |


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|  | <b>Predicate Device –<br/>Epic 100 Series SpO<sub>2</sub><br/>Sensor<br/>(ref. # K970098)</b> | <b>Predicate Device –<br/>Epic Stat-Shell<br/>Sensor Model #<br/>E502-02 (ref.<br/>K992092)</b> | <b>Proposed<br/>Epic Stat-Shell<br/>SpO<sub>2</sub> Sensor<br/>(Model E502-08)</b> |
|--|---|---|--|
| Material                                     | Cable jacket –<br>Polyurethane blend<br>Finger pad – Silicone<br>Clip – ABS                   | Cable jacket – PVC<br>Finger shell – ABS<br>Foam tape   | Cable jacket – PVC<br>Finger shell – ABS<br>Foam tape                              |
| Cable structure                              | Shielded twisted<br>pair/shielded triad   | Shielded twisted<br>pair/shielded triad   | Shielded twisted<br>pair/shielded triad  |
| Resistors                                    | Various, including<br>none  | 61.9K ohms  | none   |
| LED wavelength                               | Red 660nm nominal<br>Infrared 900nm<br>nominal  | Red 660nm nominal<br>Infrared 900nm<br>nominal  | Red 660nm nominal<br>Infrared 900nm<br>nominal                                     |
| Photodiode Active<br>Area                    | 8.23mm <sup>2</sup>   | 1.7mm <sup>2</sup>  | 8.23mm <sup>2</sup>  |
| Protection against<br>ambient light<br>noise | Opaque materials,<br>labeling warnings<br>regarding use under<br>excessive light              | Opaque materials,<br>labeling warnings<br>regarding use under<br>excessive light                | Opaque materials,<br>labeling warnings<br>regarding use under<br>excessive light   |
| Biocompatibility<br>standards                | ISO 10993-1/EN<br>30993-1   | ISO 10993-1/EN<br>30993-1   | ISO 10993-1/EN<br>30993-1  |
| Safety standards                             | EN 60601-1<br>EN 60601-1-2  | EN 60601-1<br>EN 60601-1-2  | EN 60601-1<br>EN 60601-1-2   |
| Other standards                              | EN 865/ASTM<br>F1415-92   | EN 865/ASTM<br>F1415-92   | EN 865/ASTM<br>F1415-92  |

**Performance Data & Conclusions:**

Clinical data has established product performance and accuracy within the original oximeter manufacturer's specifications.

Other bench testing was performed to verify that the device meets the same standards as the predicate device, with regard to biocompatibility, EMC, safety, and pulse oximeter standards.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

**JUN - 5 2000**

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Krista Oakes  
Vice President, RA & QA  
Epic Medical Equipment Services, Inc.  
1800 10<sup>th</sup> Street, Suite 300  
Plano, TX 75074

Re: K000831  
Stat-Shell Disposable SpO<sub>2</sub> Sensor  
Regulatory Class: II (two)  
Product Code: 74 DQA  
Dated: March 7, 2000  
Received: March 14, 2000

Dear Ms. Oakes:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Ms. Krista Oakes

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

*for Mark A. Millerson*  
James E. Dillard III

Director  
Division of Cardiovascular and  
Respiratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure



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## Statement of Indications For Use

510(k) # K000831  
Device Name: Stat-Shell Disposable SpO<sub>2</sub> Sensor

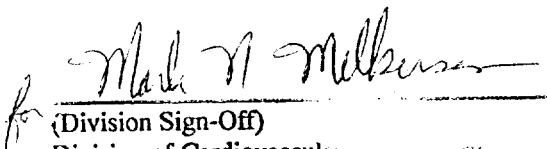
### Indications for Use:

The Stat-Shell Disposable SpO<sub>2</sub> Sensor is indicated for continuous, non-invasive functional arterial oxygen saturation and pulse rate monitoring for patients weighing more than 30 kg.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-the-Counter Use \_\_\_\_\_

  
(Division Sign-Off)  
Division of Cardiovascular  
and Neurological Devices

510(k) Number \_\_\_\_\_

K000831